REMARKS

Status Summary

Claims 150-256 are pending and under examination. Claims 174 (in part) and 175-180 are subject to an objection under 37 CFR 1.75(c) as allegedly being of improper dependent form. Claims 154-157, 177-180, 200-203, 223-226, 244-247 and 253-256 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claims 173-195 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement by introducing new matter. Claims 150-164, 167-187, 190-210, 213-233, 236-256 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Claims 243-247 and 252-256 are rejected under 35 U.S.C. § 101 as duplicative. Claims 165, 166, 211, 212, 234, and 235 are subject to an objection as depending from a rejected claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim.

Claims 165, 166, 175-176, 188, 189, 211, 212, 223-226, 234, 235, and 252-256 are canceled. Claims 150, 154-157, 173, 174, 177-180, 196, 200-203, 219, 242, and 244-247 are amended, and new claims 257-268 are added. A Replacement Figure 6 is submitted herewith. No new matter is added by any of the foregoing amendments. Reconsideration is respectfully requested in view of the claim amendments, claim cancellations, and following remarks.

Amendment to the Figures

The applicants request correction of an inadvertent error recently noted in Figure 6 as originally filed. The Replacement Figure 6 submitted herewith properly depicts residues 50-53 ("GINP") of each of the sequences for V_H; gH1; and gH4,5,6,7 in bold and italics to indicate that these residues are part of CDR-H2.

The amendment to Figure 6 is supported by the originally filed application and knowledge in the art regarding identification of CDRs within antibody sequences. Residues of CDR-H2 in gH7 as shown in Figure 6 would have been clear to one skilled in the art based upon the disclosure of CDR grafting techniques and use of donor CDR-H2 sequences defined by Kabat et al. (*see e.g.,* page 24 lines 12-25 of the originally filed application). In addition, CDR-H2 sequences of the heavy chain variable regions depicted in Figure 6 are identifiable based upon comparison to sequences in the sequence listing. For example, CDR-H2 of donor antibody

5/44 (VH) and CDR-H2 of gH5 are set forth as SEQ ID NOs: 2 and 16, respectively. Therefore, the bounds of CDR-H2 of VH and gH5 within the heavy chain variable regions depicted in Figure 6 would have been clearly understood. Additional representative CDR-H2 sequences, which are modified to remove a glycosylation site and/or to remove a reactive lysine as described in the instant specification (*see e.g.,* page 24, lines 12-25), are set forth as SEQ ID NOs: 13 and 15. Each of CDR-H2 sequences 2, 13, 15, and 16 begin with residues "GINP" and are 17 residues in length. Thus, a person skilled in the art would have understood that CDR-H2 of VH; gH1; and gH4,5,6,7 include residues 50-53 ("GINP"), and no new matter is added.

Amendments to the Claims & New Claims

Claims 150, 173, 196, 219, and 242 are each amended to specify treatment of a B cell malignancy that expresses CD22. Support for the amendment may be found in the originally filed application, including previously presented claims 165, 166, 188, 189, 211, 212, 234, and 235, now canceled.

Claims 154-157, 177-180, 200-203, and 244-247 are amended for clarity as described herein below in response to the rejection of claims under 35 U.S.C. § 112, second paragraph. The amendments to claims 177 and 178 also further limit the base claim as described in response to the claim objection. The amendments are supported by the previously presented claim language, including the sequences of the donor variable regions set forth as SEQ ID NOs: 7 and 8.

Claim 173 is amended to clarify that SEQ ID NOs: 28 and 30 set forth light chain and heavy chain sequences, respectively, rather than the variable regions thereof.

Claim 174 is amended to delete the language referring to monoclonal, chimeric, human, humanized, and single chain antibodies.

Claims 196 and 242 are amended to include additional sequences for CDR-H2 as depicted in Figure 6 of the originally filed application and amended as described herein above.

New claims 257-268 are added, which specify additional sequences for CDR-H2 as depicted in the originally filed application in Figure 4 and described at page 46, lines 1-22.

Claim Objections

Claims 174 (in part) and 175-180 are subject to an objection under 37 CFR 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Official action, pages 2-3.

In response, claims 175-176 are canceled, and claims 174 and 177-178 are amended as described herein above. Based thereon, it is respectfully requested that the objection be withdrawn.

Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 154-157, 177-180, 200-203, 223-226, 244-247 and 253-256 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctively claim the subject matter which applicant regards as the invention. Specifically, the examiner alleges that the use of the phrase "based on," as used in claim 154 to specify "wherein the human acceptor framework regions of the variable domain of the heavy chain of the antibody are based on SEQ ID NOS: 21 and 22 and comprise donor residues at positions 1, 28, 48, 72 and 97 of SEQ ID NO:8" is unclear as to whether the human acceptor framework regions of the variable domain comprises SEQ ID NOS: 21 and 22 and comprise donor residues at positions 1, 28, 48, 72 and 97 of SEQ ID NO:8. The examiner also rejects additional claims on the same basis. Official action, page 3.

Initially, as noted herein above, claims 223-226 and 253-256 are canceled, and therefore, the rejection is moot with respect to these claims.

Also noted herein above, claims 154-157, 177-180, 200-203, and 244-247 are amended to specify that the antibody comprises a framework region with residues at particular positions occupied by donor residues, and wherein the remainder of the framework region is occupied by residues of the indicated light and heavy chains (claims 154-157), light and heavy chain variable regions (claims 177-180), or framework region (claims 200-203 and 244-247) sequences. It is believed that the amended language has a clear meaning readily understood by one skilled in the art. Accordingly, it is respectfully requested that the objection of claims under 35 U.S.C. § 112, second paragraph, be withdrawn.

Rejection of Claims Under 35 U.S.C. § 112, First Paragraph - Written Description

Claims 173-195 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the examiner states that claim 173 presents new matter in describing the sequences of SEQ ID NOs: 28 and 30 as a light chain variable region and heavy chain variable region, respectively. Official action, pages 3-4.

As noted herein above, claim 173 is amended to clarify that SEQ ID NOs: 28 and 30 set forth light chain and heavy chain sequences, respectively, rather than the variable regions thereof. Claims 174-195 ultimately depend from claim 173, and therefore, also include the clarifying amendment to claim 173. Based on the foregoing, it is respectfully requested that the rejection be withdrawn.

Rejection of Claims Under 35 U.S.C. § 112, First Paragraph - Enablement

Claims 150-164, 167-187, 190-210, 213-233, 236-256 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Specifically, the examiner states that the specification, while being enabling for a method of treating a subject with a B cell malignancy which expresses CD22, it does not reasonably provide enablement for a method of treating a subject with a B cell malignancy that does not express CD22. Official action, pages 4-7.

As noted herein above, independent claims 150, 173, 196, 219, and 242 are each amended to specify treatment of a B cell malignancy that expresses CD22. Accordingly, claims 165, 166, 188, 189, 211, 212, 234, and 235 are canceled. As noted herein above, claims 175-176, 223-226, and 252-256 are also canceled. Claims 151-164 and 167-172 ultimately depend from claim 150; Claims 174, 177-187 and 190-195 ultimately depend from claim 173; claims 197-210 and 213-218 ultimately depend from claim 196; claims 220-222, 227-233 and 236-241 ultimately depend from claim 219; and claims 243-251 ultimately depend from claim 242. Therefore, each of the dependent claims include the amendment to the base claim. Accordingly, it is respectfully requested that the rejection of claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection of Claims Under 35 U.S.C. § 101

Claims 243-247 and 252-256 are rejected under 35 U.S.C. § 101 as duplicative. Official action, page 8. Claims 252-256 are canceled herein. Accordingly, withdrawal of the rejection is respectfully requested.

Conclusion

All rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a notice to that effect is earnestly solicited. If any points remain in issue, which may be best resolved through a personal or telephone interview, the examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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